IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation	)	**Case No. 14 C 1748**
	)	**MDL No. 2545**
(This document applies to *Bunting v. AbbVie Inc.*, Case No. 15 C 9699, and *Reynolds v. AbbVie Inc.*, Case No. 17 C 4117)	)	

CASE MANAGEMENT ORDER NO. 195
(Order on AbbVie's motions to exclude expert testimony and motions for summary judgment in *Bunting v. AbbVie Inc.*, No. 15 C 9699 and *Reynolds v. AbbVie Inc.*, No. 17 C 4117)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants AbbVie Inc., AbbVie Products LLC, Abbott Laboratories, Inc., and Unimed Pharmaceuticals, Inc (collectively, AbbVie) manufacture AndroGel, one of the TRT products at issue in this litigation. Before the Court are AbbVie's motions to exclude expert testimony and for summary judgment in two cases: *Bunting v. AbbVie Inc.*, No. 15 C 9699, and *Reynolds v. AbbVie Inc.*, No. 17 C 4117. Juliana Bunting alleges that her late husband Kenneth Bunting's use of AndroGel caused his death from a heart attack in April 2014. Tony Reynolds alleges that his use of AndroGel caused him to suffer a stroke in January 2014.

AbbVie has moved under Federal Rule of Evidence 702 to exclude the testimony of expert witness Dr. Hossein Ardehali in the *Reynolds* case and the testimony of expert

witness Dr. Joshua Sharlin in both *Bunting* and *Reynolds*. AbbVie also has moved for summary judgment on all of the plaintiffs' remaining claims or, in the alternative, on certain categories of damages that AbbVie contends are limited by state law. For the following reasons, the Court grants AbbVie's motion to exclude Dr. Ardehali's marketing opinion testimony but otherwise denies the motion to exclude. The Court grants AbbVie's motions for summary judgment with respect to the availability of punitive and noneconomic damages in *Reynolds* and punitive damages in *Bunting* but otherwise denies the motions for summary judgment.

Background

The Court assumes familiarity with the background as set out in its prior case management orders and therefore discusses only those details relevant to the motions at issue. The facts are undisputed except where otherwise stated.

Kenneth Bunting began using AndroGel in 2013 and died from a heart attack in April 2014. Juliana Bunting filed suit in October 2014 as the representative of her late husband's estate and on her own behalf. She has asserted wrongful death and survival claims of strict liability, negligence, breach of warranty, fraud, redhibition, consumer protection, and unjust enrichment. She also seeks punitive damages. AbbVie moved for summary judgment on all claims. In February 2023, the Court granted summary judgment for AbbVie on all of the Estate's claims and on Bunting's wrongful death action to the extent it is premised on claims of unjust enrichment, redhibition, and breach of warranty. *See In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2023 WL 1800079, at *8 (N.D. Ill. Feb. 7, 2023) (hereinafter CMO 192). The

Court denied summary judgment on Bunting's wrongful death action as it related to the underlying strict liability, negligence, fraud, and consumer protection claims. *Id.*

Tony Reynolds began using AndroGel on January 15, 2014 after his doctor, Garvin Chastain, prescribed it to treat fatigue and low libido. On January 21, 2014, Reynolds suffered a stroke. Dr. Chastain testified during his deposition that he was aware of some studies regarding the cardiovascular risk of TRT products but that he believed the evidence was inconclusive. He also gave conflicting answers regarding whether a warning about AndroGel's cardiovascular risks would have affected his decision to prescribe the drug for Reynolds.

Reynolds had a number of preexisting conditions that put him at risk for adverse cardiovascular events such as a stroke. Over Thanksgiving 2013, before Reynolds began using AndroGel, he experienced dysarthria (slurred speech), which can be a stroke symptom. Brain scans taken after Reynolds's stroke in 2014 showed evidence that Reynolds may have had a prior transient ischemic attack, sometimes referred to as a "mini-stroke."

Reynolds filed suit in April 2017 asserting claims for strict liability, negligence, breach of warranty, fraud, redhibition, consumer protection, and unjust enrichment. He also seeks punitive damages. AbbVie moved for summary judgment on all claims. In February 2023, the Court granted summary judgment in favor of AbbVie on Reynolds's redhibition, unjust enrichment, and consumer protection claims but allowed his remaining claims to proceed. *See In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2023 WL 1800078, at *5 (N.D. Ill. Feb. 7, 2023).

In support of their claims, both Bunting and Reynolds rely on two expert

witnesses: Dr. Hossein Ardehali, a cardiovascular medicine expert, and Dr. Joshua Sharlin, a regulatory expert. Dr. Ardehali's opinion is that AndroGel was a substantial cause of Kenneth Bunting's heart attack and Reynolds's stroke. Dr. Ardehali's report, however, made no reference to Reynolds's dysarthria incident or the brain imaging evidence. Dr. Sharlin's opinion is that AbbVie should have included a warning regarding the cardiovascular risks of AndroGel and that it failed to prudently respond to warning signs that the drug was dangerous. To reach this conclusion, Dr. Sharlin relied in part on data from the FDA's Adverse Event Reporting System (FAERS) database, which tracks reports of adverse events related to various medications. Dr. Sharlin asserts that AbbVie ignored certain FAERS data that a prudent pharmaceutical manufacturer would have considered when monitoring the safety of its drug. Specifically, he states that AbbVie considered only adverse events connected with AndroGel and disregarded adverse events associated with similar TRT products.

Discussion

A. Admissibility of expert testimony

1. Dr. Ardehali's specific causation opinion

The parties agree that Tennessee law governs Reynolds's claims. Under Tennessee law, a plaintiff must show that "the defendant's conduct was 'a substantial factor in bringing about the harm being complained of.'" *Barnes v. Kerr Corp.*, 418 F.3d 583, 588–89 (6th Cir. 2005) (quoting *McClenahan v. Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991)) (internal quotations omitted). The parties refer to this element of Reynolds's claim as specific causation. To satisfy the specific causation requirement, Reynolds relies on the expert testimony of Dr. Ardehali. AbbVie argues that Dr.

Ardehali's testimony that AndroGel was a substantial cause of Reynolds's stroke should be excluded under Rule 702 because it is unreliable. Specifically, AbbVie contends that Dr. Ardehali failed to account for the fact that Reynolds likely suffered stroke symptoms and/or a "mini-stroke" before he began taking AndroGel and the fact that Reynolds took AndroGel for only five to seven days before his stroke.

Under Rule 702, which governs the admissibility of expert testimony, a court must evaluate "(1) the proffered expert's *qualifications*; (2) the *reliability* of the expert's methodology; and (3) the *relevance* of the expert's testimony." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017). Only the second consideration is at issue in this case. To determine the reliability of expert testimony, Rule 702 directs courts to consider whether the expert's opinion is "based on sufficient facts or data," whether the opinion is "the product of reliable principles and methods," and whether that methodology has been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702(b)–(d). This analysis, however, must focus "solely on principles and methodology, not on the conclusions that they generate." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993); *see also Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013) ("Rule 702's requirement that the district judge determine that the expert used reliable methods does not ordinarily extend to the reliability of the conclusions those methods produce—that is, whether the conclusions are unimpeachable."). That is because "[t]he jury must still be allowed to play its essential role as the arbiter of the weight and credibility of expert testimony." *Stollings*, 725 F.3d at 765.

Dr. Ardehali's expert report explained that Reynolds had a number of preexisting risk factors for an ischemic stroke, including "poorly controlled diabetes, being

overweight, and smoking." Ardehali Expert Rep. at 13. Dr. Ardehali concluded, however, that "testosterone therapy was a substantial factor in Mr. Reynolds' catastrophic stroke" and that "[b]ut for the use of AndroGel testosterone product, Mr. Reynolds would not have experienced the stroke." *Id.* Specifically, Dr. Ardehali opined that AndroGel was the catalyst that, combined with Reynolds's underlying conditions, led to the stroke that Reynolds suffered on January 14. *See id.* at 13–14 (explaining that AndroGel "caused a hypercoagulable state" which "increased risk of plaque rupture" and "caused increased risk of larger thrombus formation" and that the adverse effects of AndroGel were intensified by Reynolds's "conditions of obesity and hyperinflammation"). In sum, Dr. Ardehali's opinion is that "AndroGel therapy was a substantial factor in causing [Reynolds's] vascular event because of its effect on coagulation under circumstances of a systemic chronic inflammatory disease." *Id.*

AbbVie argues that Dr. Ardehali's opinion should be excluded because his report does not mention or analyze the possibility that Reynolds may have suffered a transient ischemic attack, often referred to as a "mini-stroke," before he began taking AndroGel. Specifically, AbbVie points to the fact that (1) Reynolds experienced a stroke symptom known as dysarthria (slurred speech) in November 2013; and (2) brain imaging scans taken after Reynolds's January 2014 stroke showed evidence of preexisting lunar infarctions, which can be evidence of an earlier transient ischemic attack. When asked about this during his deposition, Dr. Ardehali agreed that a past mini-stroke puts a patient at greater risk of suffering a future stroke. He also agreed that the dysarthria that Reynolds experienced in November 2013 was "an important piece of his clinical record and [ ] should have been included" in his report, and he acknowledged that he

"didn't include a risk factor, the fact that he had a mini-stroke." Pls.' Resp. to Mot. to Exclude, Ex. A (Ardehali Dep.) at 143:6–9, 143:15–20. Dr. Ardehali stated, however, that the omitted information did not change his opinion that AndroGel was a substantial cause of the January 2014 stroke.

The fact that Dr. Ardehali overlooked, in his report, the likelihood that Reynolds experienced a transient ischemic attack before he began taking AndroGel is potentially significant evidence to be considered in weighing Dr. Ardehali's causation opinion. But the Court is not persuaded that this missing item warrants the exclusion of Dr. Ardehali's testimony. Courts may consider "[w]hether the expert has adequately accounted for obvious alternative explanations" when determining the reliability of an expert's methodology. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013) (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment). This does not mean, however, that to be admissible, an expert's opinion must "rule out every alternative cause." *Id.* Rather, "objections that . . . experts failed to consider facts (or that they placed too great an emphasis on certain facts over others) 'generally go to the weight of the expert's opinion, not its admissibility.'" *Africano v. Atrium Med. Corp.*, 561 F. Supp. 3d 772, 778 (N.D. Ill. 2021) (quoting *Jordan v. Dominick's Finer Foods*, 115 F. Supp. 3d 950, 963 (N.D. Ill. 2015)); *see also Burton v. Am. Cyanamid*, 362 F. Supp. 3d 588, 601 (E.D. Wis. 2019) ("That [an expert] did not consider and exclude *all* possible factors . . . goes to the weight and not the admissibility of his testimony.").

In this case, Dr. Ardehali has consistently recognized that Reynolds was at high risk of a stroke due to his preexisting conditions, and he has explained why he nonetheless believes that AndroGel was a substantial cause of the January 2014

stroke. And although Dr. Ardehali's report did not reference Reynolds's prior transient ischemic attack symptoms, when asked about this during his deposition he testified that that these additional facts did not alter his opinion regarding causation. "The possibility that a cause other than [AndroGel] was ultimately responsible for [Reynolds's] injury is properly left for exploration on cross-examination." *Gayton v. McCoy*, 593 F.3d 610, 619 (7th Cir. 2010).

AbbVie also argues that Dr. Ardehali's opinion is unreliable because he does not explain how Reynolds's short-term use of AndroGel—only between five to seven days—could have caused his stroke. But there is no indication that Dr. Ardehali was unaware of or ignored this short-term timeframe when forming his opinion. His expert report clearly states that Reynolds was prescribed AndroGel on January 15, 2014 and that he began using the drug that same day. Ardehali Expert Rep. at 4. And during his deposition, Dr. Ardehali reaffirmed his belief that even this short-term AndroGel use was sufficient to trigger the "hypercoaguable state," "increased risk of plaque rupture," and "thrombus formation" that he believes led to Reynolds's stroke. Pls.' Resp. to Motion to Exclude, Ex. A (Ardehali Dep.) at 153:16–22, 155:19–156:4. The Court therefore sees no viable basis to exclude Dr. Ardehali's opinion on this ground.

In sum, the Court concludes that Dr. Ardehali's specific causation opinion is sufficiently reliable to meet the requirements of Rule 702. The weight to be given to that opinion is appropriately a matter for consideration by the jury. The flaws that AbbVie highlights are more properly addressed through the "traditional and appropriate means of attacking shaky but admissible evidence": "[v]igorous cross-examination,

presentation of contrary evidence, and careful instruction on the burden of proof." *Schultz*, 721 F.3d at 431 (quoting *Daubert*, 509 U.S. at 596).

2. Dr. Ardehali's marketing opinion

AbbVie also argues that the Court should exclude Dr. Ardehali's testimony that AbbVie's marketing techniques caused Dr. Chastain to prescribe AndroGel to Reynolds. In his report, Dr. Ardehali included a section titled "AbbVie's Diabetes-Related Marketing" in which he discussed various methods through which AbbVie targeted and marketed AndroGel to certain physicians with significant numbers of diabetes patients, including Dr. Chastain. Ardehali Expert Rep. at 10. Based on this information, Dr. Ardehali testified during his deposition that "the fact that this was given to this patient, to me, is because of the marketing that the companies were doing." Pls.' Resp. to Mot. to Exclude, Ex. A (Ardehali Dep.) at 136:17–23. AbbVie argues that Dr. Ardehali is not qualified to offer this opinion because "[h]e concedes that he has no expertise in marketing, that he does not review marketing materials as part of his practice, [and] that he made no study about pharmaceutical marketing for this case." Mot. to Exclude at 8. In addition, AbbVie emphasizes that Dr. Ardehali never consulted the deposition testimony of Dr. Chastain regarding how or why he decided to prescribe AndroGel to Reynolds.

The Court agrees that Dr. Ardehali is not qualified to offer expert testimony regarding the impact of AbbVie's marketing techniques on Dr. Chastain's decision to prescribe AndroGel to Reynolds. To determine the admissibility of an expert's testimony, "[t]he question we must ask is not whether an expert witness is qualified in general, but whether his 'qualifications provide a foundation for [him] to answer a

specific question.'" *Gayton*, 593 F.3d at 617 (quoting *Berry v. City of Detroit,* 25 F.3d 1342, 1351 (6th Cir. 1994)). Dr. Ardehali does not claim to be an expert in marketing, psychology, or another relevant field. Nor has Reynolds pointed to any other basis upon which the Court might find that Dr. Ardehali holds "scientific, technical or other specialized knowledge" regarding pharmaceutical marketing that would "help the trier of fact to understand the evidence" in this case. Fed. R. Evid. 702(a). The Court concludes that Reynolds has failed to establish that Dr. Ardehali is qualified to offer an opinion regarding how AbbVie's marketing techniques may have influenced Dr. Chastain to prescribe testosterone therapy to Reynolds. The Court therefore grants AbbVie's motion to exclude Dr. Ardehali's marketing-related opinions under Rule 702.

3. Dr. Sharlin's failure-to-warn opinion

AbbVie next argues that the Court should exclude the testimony of the plaintiffs' regulatory expert, Joshua Sharlin, Ph.D. First, AbbVie asserts that Dr. Sharlin's testimony is inadmissible because he ignored evidence by failing to cite to certain studies. Second, AbbVie argues that Dr. Sharlin's opinion is unreliable because he relied in part on information from the FAERS database but failed to account for potential duplicate entries in that database. As AbbVie acknowledges, however, the Court has already declined to exclude Dr. Sharlin's opinion on this same ground in another case in this MDL. See *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2023 WL 1808409, at *7 (N.D. Ill. Feb. 7, 2023) (hereinafter CMO 193). AbbVie does not offer any basis for the Court to reach a different conclusion here. The Court therefore declines to exclude Dr. Sharlin's opinion on this basis.

The only new argument that AbbVie advances in its motion is that Dr. Sharlin's opinion is unreliable because he did not conduct a statistical analysis to determine whether the FAERS adverse events data that he contends AbbVie ignored "would have changed any determination made by AbbVie or the FDA regarding AndroGel or TRT's overall risk." Mot. to Exclude at 11.

The FAERS database tracks reports of adverse events related to various medications. In his report, Dr. Sharlin asserts that AbbVie improperly limited its review of the FAERS database by failing to review "adverse events related to the use of other drugs (i.e., TRTs) in the same class (androgen) as AndroGel as determined by the FDA." Sharlin Expert Rep. at 52–53. According to Dr. Sharlin, this led AbbVie to exclude "the majority of the safety data about adverse cardiovascular events associated with testosterone," despite the fact that a "reasonably prudent manufacturer would have considered" this data. *Id.*

It is undisputed that Dr. Sharlin never conducted any statistical analysis to determine whether the omitted data points would have shown that there was a dangerous link between TRT drugs and adverse cardiovascular events. As a result, AbbVie argues, Dr. Sharlin cannot reliably testify that AbbVie should have warned users about the cardiovascular risks of AndroGel, as he has not shown a definitive link between the FAERS data and that conclusion.

The Court disagrees that Dr. Sharlin's failure to conduct a statistical analysis regarding "whether or how these purported additional adverse events would have changed the risk profile of TRT" renders his opinion inadmissible. Mot. to Exclude at 10. First, Dr. Sharlin's report straightforwardly states the same proposition that AbbVie

argues renders his opinion inadmissible: that "it is difficult to make final conclusions about causation based just on" the number of adverse events in FAERS "because the total number of men using these drugs is unknown (i.e., a percent of injuries among all drug users cannot be calculated)." Sharlin Rep. at 57. The plaintiffs likewise concede that adverse event data "generally does not" lead to "a final conclusion about causation." Pls.' Resp. to Mot. to Exclude at 11. Rather, they argue that the purpose of Dr. Sharlin's testimony regarding the omitted data is to show that AbbVie did not act as a prudent manufacturer because it failed to properly monitor safety data and conduct further investigations in response to troubling trends. Because Dr. Sharlin's testimony is not that the FAERS data shows that AndroGel causes adverse cardiovascular events, AbbVie cannot complain that he has not reliably established such a causal connection.

Second, the Court disagrees with the premise that an expert's methodology is unreliable solely because a different, more complex analysis might disprove the expert's conclusion. "The critical inquiry is whether there is a connection between the data employed and the opinion offered." *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013). As this Court previously concluded, "there is a rational connection between the adverse events data and Dr. Sharlin's conclusion that AbbVie did not sufficiently investigate the adverse events suggesting there were cardiovascular risks to AndroGel." *See* CMO 193, 2023 WL 1808409, at *7. Although a statistical analysis of the kind that AbbVie proposes could be helpful in determining the significance of the data that AbbVie failed to consider, that does not render Dr. Sharlin's opinion inadmissible. To the extent that AbbVie contends that the omitted evidence would have had no effect on their safety conclusions related to AndroGel, that is a proposition that it

can advance at trial through cross-examination and presentation of its own expert testimony. The Court denies AbbVie's motion to exclude Dr. Sharlin's expert testimony.

B. Preemption

In its motion for summary judgment, AbbVie seeks to "incorporate[ ]" earlier arguments made in other cases in this MDL that the plaintiffs' failure-to-warn claims are preempted by "federal law." Def.'s Mem. in Supp. of Summ. J. at 14. AbbVie acknowledges that the Court overruled these arguments but asserts that there are two reasons the Court should reach a different outcome in this case. First, it argues that Bunting's claim is barred because Kenneth Bunting's injury occurred in April 2014, after "the FDA issued a January 2014 statement providing its complete view of the scientific evidence as to AndroGel—and any risks of AndroGel—at the time." *Id.* AbbVie fails to explain, however, what significance the FDA's 2014 statement has regarding the federal preemption question. The Court's best guess is that AbbVie is attempting to raise the same argument that it has made previously: that the 2014 announcement somehow indicates that the FDA would not have approved any additional warnings proposed by AbbVie. *See* CMO 193, 2023 WL 1808409, at *4 ("AbbVie also argues that Loreto's failure to warn claim is preempted because it could not have provided a stronger warning" and that "the preemption analysis is different in this case because Loreto's injury occurred after the FDA's January 2014 safety announcement."). The Court has previously rejected this argument. *See id.* (holding that the preemption analysis is "no different for Loreto than it was for the earlier bellwether plaintiffs, as AbbVie does not assert that it made changes to AndroGel's label between the bellwether plaintiffs' injuries and Loreto's February 2014 heart attack"). And even if the Court were inclined

to reconsider its previous rulings, AbbVie has offered no explanation regarding why the 2014 announcement amounts to "clear evidence that the FDA would have rejected an effort by AbbVie to add the requested labeling changes to the AndroGel label." *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 1836435, at *11 (N.D. Ill. May 8, 2017) (hereinafter CMO 47).

AbbVie also argues that the preemption analysis is different in this case because "results from the recent TRAVERSE study confirm that men using testosterone did not experience a greater number of major adverse cardiac events compared with those who received a placebo." Def.'s Mem. in Supp. of Summ. J. at 15. But AbbVie does not explain how results from a 2023 study have any bearing on what the FDA would or would not have approved many years earlier. Moreover, to find preemption on this basis, the Court would have to determine that the TRAVERSE results "disprove[ ] the relationship" between AndroGel and adverse cardiovascular events that plaintiffs and their experts have asserted. This is a hotly contested factual issue in this case that cannot be resolved on summary judgment. In sum, AbbVie has failed to show that is entitled to summary judgment based on preemption.

C. Causation

AbbVie argues that it is entitled to summary judgment on all of Reynolds's claims because he cannot show that AndroGel caused his injuries. AbbVie's first argument is if the Court excludes Dr. Ardehali's testimony, Reynolds cannot prove causation. This argument fails in light of the Court's denial of AbbVie's motion to exclude Dr. Ardehali's specific causation testimony.

AbbVie's second argument is that Reynolds cannot show that its claimed failure

to warn caused his injuries. To prevail on a failure-to-warn claim under Tennessee law, a plaintiff must show not only that the warning was defective but also "that the inadequate labelling proximately caused the claimed injury." *Barnes*, 418 F.3d at 590 (quoting *Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1329 (6th Cir. 1992)). In other words, a plaintiff must "establish that, had additional warnings been given, the [plaintiff] would not have sustained [his] injuries." *King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000).

AbbVie argues that Reynolds cannot carry his burden on this element because he cannot show that a warning regarding AndroGel's alleged risks would have caused his prescribing physician, Dr. Chastain, to act differently. In particular, AbbVie cites to the following portion of Dr. Chastain's deposition:

> Q: Would you have done anything differently with respect to Mr. Reynolds' AndroGel prescription in January 2014 or your discussion with him at that time in light of any information you know today?
>
> A: Well, no. No, I wouldn't.

Pls.' Opp. to Summ. J., Ex. F (Chastain Dep.) at 82:19–24. The problem with this argument, for summary judgment purposes, is that it disregards other portions of Dr. Chastain's testimony that point in a different direction. For example:

> Q: And the fact that there could be a risk of stroke with AndroGel, that's information that you would have liked to have available to you as a resource when you made the risk benefit analysis regarding Tony's prescription, right?
>
> A: Well, I mean, yeah, any information you have is valuable. Particularly when you're starting a new drug.

Id. at 104:23–105:5 (objection omitted).

> Q: Is it fair to say that if AbbVie had warned you about the risk of stroke you wouldn't have prescribed AndroGel for Tony?

> A: Well, I would have included that in my decision making process. I can't say. I can't say. You know, it would depend on how – it would have depended also on how Tony thought about that additional information. You know, I think that would have probably been the most important thing. It would also been nice to known [sic] what data that was based on, you know. And since the medical literature is basically all over the place on that, you know, with some data showing increased risks and some not, I don't exactly know what they base that on.

Id. at 196:9–107:10 (objection omitted).[1] These exchanges suggest that a different warning may have led Dr. Chastain to a different outcome, either because he would have declined to prescribe AndroGel or because he would have given Reynolds a stronger admonition that could have led Reynolds to pass on the medication. In addition, during his deposition, Dr. Chastain agreed that if he had known about the FDA's concerns about off-label promotion of AndroGel, he would have factored that into his decision to prescribe AndroGel to Reynolds. All of this is sufficient at the summary judgment stage to show that the causation issue raised by AbbVie is genuinely disputed.

AbbVie also argues that Dr. Chastain's testimony shows that he was aware of the risks that the omitted warning would have covered. But Dr. Chastain consistently testified that he was *not* aware in 2014 that AndroGel increased the risk of stroke or other major adverse cardiovascular events. Rather, his understanding was that the evidence of risk was inconclusive. For example:

> Q: When you first prescribed testosterone replacement therapy for Mr. Reynolds in 2014, was it your understanding that testosterone replacement therapy carried an increased risk of adverse cardiovascular events, including stroke?

[1] During the deposition, AbbVie objected to these questions, but it did not articulate any basis for the objection. Before the Court, AbbVie has not suggested that this testimony by Dr. Chastain would be inadmissible.

> A: No. I think the evidence is mixed on that. The literature. I don't think there's any definitive evidence that it does.

Id. at 39:12–19. Arguably, then, Dr. Chastain is precisely the audience that could have benefited from the type of warning that Reynolds alleges AbbVie should have included, because it might have alerted him that the risk had been substantiated more than he previously believed. In addition, although Dr. Chastain had some knowledge of a possible connection between TRT medication and strokes, this does not mean that he had the same degree of knowledge that an adequate warning from AbbVie would have provided. For example, after being shown AndroGel's updated 2015 label which included a warning about a possible stroke risk, Dr. Chastain agreed that the "known risks" he discussed with Tony in 2014 "wouldn't have included the information that's stated [on AndroGel's label] in regards to that." *Id.* at 113:25–114:11.

The Court concludes that Reynolds's evidence, though certainly not overwhelming, would permit a reasonable jury to find that AbbVie's failure to warn proximately caused his injury.

D. Punitive damages

1. Availability of punitive damages in *Reynolds*

AbbVie argues that Reynolds cannot seek punitive damages because, under Tennessee law, "punitive damages shall not be awarded in a civil action involving a drug or device if the drug or device which allegedly caused the claimant's harm . . . [w]as manufactured and labeled in relevant material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act . . . or the Public Health Service Act." Tenn.

Code § 29-39-104(d)(1)(A). AbbVie asserts that this punitive damages bar applies because AndroGel—including its labeling and warnings—was approved by the FDA at the time of Reynolds's injury. Reynolds argues that (1) AndroGel was not labeled in accordance with the terms of its FDA approval, and (2) he is entitled to an exception because AbbVie withheld and/or misrepresented information to the FDA.

Reynolds does not develop the first argument beyond stating in a single sentence that "pharmaceutical manufacturers have a duty to monitor for potential risks and a duty to update the warnings in their prescribing information when they become aware of a potential risk." Pls.' Opp. to Summ. J. at 10. He does not cite to any specific "terms of an approval or license" that AbbVie violated. Nor does he cite any case law or develop any substantive legal argument for the proposition that a manufacturer's failure to proactively update a drug's warnings means that the drug was not "manufactured and labeled . . . in accordance with the terms of an approval or license" issued by the FDA. The Court concludes that section 29-39-104(d)(1)(A) applies.

Reynolds argues that he nevertheless may recover punitive damages because the statute includes an exception that permits punitive damages "if, at any time before the event alleged to have caused harm, the manufacturer, in violation of applicable regulations of the food and drug administration: (A) Withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered; or (B) misrepresented to the food and drug administration information of that type." Tenn. Code 29-39-104(d)(2).

AbbVie argues that this exception is invalid because it is preempted by federal law. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001), the

Supreme Court held that state-law causes of action that arise "solely from the violation of FDCA requirements" are impliedly preempted by the FDCA. The plaintiffs in that case alleged that a medical device manufacturer had "made fraudulent representations to the FDA as to the intended use of the [device] and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment." *Id.* at 346–47. The Supreme Court distinguished these "fraud-on-the-FDA" claims from traditional state-law tort claims such as negligence. In fraud-on-the-FDA claims, the plaintiff's claim "exist[s] solely by virtue of" an FDCA requirement and the plaintiff must prove that the defendant violated the FDCA as a "critical element in their case." *Id.* at 353. Traditional tort claims, in contrast, assert that the defendant violated a duty of care that might "parallel federal safety requirements" but does not depend on the violation of any federal statute or regulation. *Id.* at 352–53. The Court concluded that fraud-on-the-FDA claims are impliedly preempted because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

Courts applying *Buckman* have mainly addressed whether claims, or statutory defenses to claims, are preempted based on the fraud-on-the-FDA doctrine. *See, e.g.*, *DiCroce v. McNeil Nutritionals, LLC*, -- F.4th --, No. 22-1910, 2023 WL 6056144, at *4 (1st Cir. Sept. 18, 2023); *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040 (9th Cir. 2022); *Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 967 (6th Cir. 2004). That is not the question in this case; Reynolds's underlying failure-to-warn claim is not a fraud-on-the-FDA claim. Rather, the question is whether the Tennessee statutory exception that arguably permits Reynolds to seek *punitive*

damages is invalid based on *Buckman*. Courts analyzing statutory schemes like Tennessee's, which generally bar punitive damages for FDA-approved drugs but create an exception for situations in which defendants have violated FDA regulations, have come to different conclusions regarding preemption. *Compare, e.g.*, *Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 610 (E.D.N.Y. 2011) (holding that a New Jersey statute permitting punitive damages only if manufacturer "knowingly withheld or misrepresented information required to be submitted under [the FDA's] regulations" was not impliedly preempted), *with McDarby v. Merck & Co.*, 401 N.J. Super. 10, 93, 949 A.2d 223, 275 (App. Div. 2008) (holding that the New Jersey statute's provisions "impinge upon federal statute and regulation to the same extent that was recognized in *Buckman*"), *and Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (concluding that "the rationale that led the *Buckman* court to find implied preemption applies with equal force" to an Arizona statute permitting punitive damages only if the defendant "withheld from or misrepresented" information to the FDA in violation of FDA regulations).

The Tennessee statute at issue here requires, as an essential prerequisite to the recovery of punitive damages, that the defendant "withheld" or "misrepresented" information from the FDA "in violation of applicable [FDA] regulations." Tenn. Code § 29-39-104(d)(2). This language expressly incorporates a violation of the FDCA as a "critical element" of the recovery of punitive damages. *Buckman*, 531 U.S. at 353. Like the claims at issue in *Buckman*, the availability of punitive damages in Reynolds's case "exist[s] solely by virtue of" an FDCA violation. *Id.* In other words, if the FDCA did not exist, Reynolds would have no independent grounds for recovering punitive damages

under Tennessee law. The Court concludes on this basis that the principles in *Buckman* extend to the exception at issue here and that section 29-39-104(d)(2), as applied here, is impliedly preempted by the FDCA.

Because punitive damages are unavailable, the Court need not address the parties' arguments regarding whether Tennessee law imposes a maximum limit on the amount of punitive damages Reynolds can recover.

2. Cap on noneconomic damages in *Reynolds*

AbbVie argues that, under section 29-39-102 of the Tennessee Code, Reynolds may recover no more than $750,000 in noneconomic damages. Reynolds argues that this cap violates his right to a trial by jury under the Tennessee Constitution and the U.S. Constitution. Reynolds's state constitutional argument is foreclosed by *McClay v. Airport Management Services, LLC*, 596 S.W.3d 686 (Tenn. 2020), in which the Tennessee Supreme Court held that section 29-39-102 does not violate the right to a jury under the Tennessee Constitution. Reynolds does not develop his federal constitutional argument with any argument or legal authority. He has therefore forfeited the point. "Arguments that are underdeveloped, cursory, and lack supporting authority are waived." *Shipley v. Chi. Bd. of Election Comm'rs*, 947 F.3d 1056, 1063 (7th Cir. 2020). The Court concludes that the $750,000 cap on noneconomic damages applies.

3. Availability of punitive damages in *Bunting*

The parties dispute whether Bunting is entitled to seek punitive damages in conjunction with her wrongful death claim. Until recently, Illinois law barred a plaintiff

from seeking punitive damages in a wrongful death action.[2] *See Vincent v. Alden Strathmoor, Inc.*, 241 Ill. 2d 495, 503, 948 N.E.2d 610, 614 (2011) ("[A]s a general rule, the right to seek punitive damages for personal injuries does not survive the death of the injured party."). Missouri's wrongful death statute, in contrast, authorizes a plaintiff to "seek damages based on 'aggravating circumstances,'" which "the Missouri Supreme Court has explained . . . are the equivalent of punitive damages." *Hersh v. CKE Rest. Holdings, Inc.*, 571 F. Supp. 3d 1046, 1053 (E.D. Mo. 2021) (citing Mo. Rev. Stat. §§ 537.080, 537.090 and *Bennett v. Owens-Corning Fiberglas Corp.*, 896 S.W.2d 464, 466 (Mo. 1995)). AbbVie argues that Illinois law governs the availability of punitive damages; Bunting argues that Missouri law should apply.

The parties agree that Missouri choice-of-law rules apply. Missouri follows the "most significant relationship" test of the Restatement (Second) of Conflict of Laws. In wrongful death actions, "the law of the state where the injury occurred will apply to determine the rights and liabilities of the parties 'unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in [section] 6 to the occurrence and the parties, in which event the local law of the other state will be applied.'" *Livingston v. Baxter Health Care Corp.*, 313 S.W.3d 717, 721 (Mo. Ct. App. 2010) (quoting Restatement (Second) of Conflict of L. § 175) (1971)). Those principles are "(a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the

[2] Bunting points out that Illinois recently changed its law to authorize punitive damages in wrongful death actions, but that change does not apply to suits that have already been filed. See H.B. 219, 103d Gen. Assem. (Ill. 2023).

protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied." *Id.* (quoting Restatement § 6(2)). Missouri also recognizes "that choice of law questions are determined on an issue-by-issue basis and that 'the state where the tort was committed may not be the state with the superior interest in such an issue as the amount of damages a jury may return on the cause of action.'" *Id.* (quoting *Nelson v. Hall*, 684 S.W.2d 350, 352 (Mo. Ct. App. 1984)).

AbbVie argues that Illinois law should govern the question of punitive damages because it is headquartered in Illinois and made the relevant decisions regarding the warnings associated with AndroGel in Illinois. In AbbVie's view, this means that Illinois has a more significant relationship on the issue of punitive damages, as the purpose of punitive damages is to punish the defendant, not to compensate the plaintiff. Bunting, on the other hand, argues that Missouri has the most significant interest "in protecting its citizens from bad conduct that occurs in the state, even if that bad conduct was cooked up elsewhere" and perhaps "*especially* when that bad conduct was cooked up elsewhere." Pls.' Opp. to Summ. J. at 14–15.

The Court addressed a similar choice-of-law question under Illinois law in a decision regarding the availability of punitive damages against AbbVie for the bellwether plaintiffs in this MDL. *See* CMO 47, 2017 WL 1836435, at *21–23. Like Missouri, Illinois applies the Restatement's most significant relationship test. The Court noted that, as in this case, "the most significant contacts occurred both in plaintiffs' home states (where the injuries occurred) and in AbbVie's home state (where the conduct that allegedly caused the injury took place) and therefore d[id] not favor one party over the

other." *Id.* at *21. The Court found, however, "that Illinois ha[d] the greatest interest in governing the determination of punitive damages" because "[p]unitive damages serve a public goal of punishing the defendant for its wrongdoing and protecting the public from future misconduct, either by the defendant or by others." *Id.* As a result, the Court concluded that Illinois law applied because "the state in which a defendant is domiciled therefore tends to have a stronger policy interest in whether punitive damages are available than the state in which the plaintiff's injury occurred." *Id.*

The parties do not cite, and the Court has not found, any Missouri decision that squarely addresses this question. At the very least, however, a handful of Missouri court decisions indicate that Missouri agrees that a state has "a definite interest in having the full extent of its laws control the activities within its borders of corporations which locate their principal place of business in that state" and that this interest should be considered in the choice-of-law inquiry regarding punitive damages. *State ex rel. Broglin v. Nangle*, 510 S.W.2d 699, 703 (Mo. 1974) (en banc); *Livingston*, 313 S.W.3d at 723 ("[B]ecause [the defendant] conducts business in Kansas, Kansas arguably has an interest in having its statutory cap applied in order to protect a corporation doing business in Kansas from an excessive jury verdict."); *Brovont v. KS-I Med. Servs., P.A.*, 622 S.W.3d 671, 692 (Mo. Ct. App. 2020) ("[The defendant] is a Missouri company that contracted with physicians in Missouri . . . . Missouri has a legitimate interest in punishing and deterring Missouri companies from wrongfully discharging their employees."). In addition, like Illinois, Missouri recognizes that "[p]unitive damages . . . have as their purpose, not the compensation of the plaintiff, but the punishment of the defendant and the deterrence of the offending conduct in the future." *Bradshaw v.*

Deming, 837 S.W.2d 592, 594 (Mo. Ct. App. 1992). The Court therefore concludes that under Missouri choice-of-law rules, Illinois, AbbVie's home state and the state where the conduct allegedly causing the injury occurred, has a greater interest in determining whether punitive damages are available than Missouri, where the injury occurred.

Because the parties agree that Illinois law bars punitive damages in this case, the Court grants AbbVie's motion for summary judgment on the issue of punitive damages.

4. Revival of survival action

Finally, Bunting argues that the Court should reverse its previous grant of summary judgment for AbbVie on the survival action brought by the Estate of Kenneth Bunting because Illinois recently passed a bill that authorizes punitive damages in survival actions. The plaintiffs previously agreed, however, that both Bunting's wrongful death claim and the Estate's survival claims were governed by Missouri law. The Court granted summary judgment for AbbVie on the Estate's survival claims because Missouri does not permit such actions. CMO 192, 2023 WL 1800079, at *3. Bunting cannot change course now based on the collateral consequences of her previous decision. Moreover, even if the Court were inclined to revisit the point, Bunting has articulated no legal argument for why Missouri choice-of-law rules permit the Court to apply Illinois law to the liability component of the Estate's survival action claims. *See Dorman v. Emerson Elec. Co.*, 23 F.3d 1354, 1358 (8th Cir. 1994) (explaining the Missouri law "presumption that the state with the most significant relationship is the state where the injury occurred, absent an overriding interest of another state based on the factors

articulated in section 6 [of the Restatement (Second) of Conflict of Laws]"). The Court therefore declines to reverse its judgment on the Estate's claims.

Conclusion

For the foregoing reasons, the Court grants AbbVie's motion to exclude Dr. Ardehali's testimony on AbbVie's marketing techniques but otherwise denies the motion [*Bunting* dkt. 60; *Reynolds* dkt. 42]. The Court grants AbbVie's motions for summary judgment [*Bunting* dkt. 62; *Reynolds* dkt. 44] with respect to the availability of punitive damages and noneconomic damages in *Reynolds* and punitive damages in *Bunting* but otherwise denies the motions for summary judgment. These cases will be returned in due course to their home districts.

MATTHEW F. KENNELLY
United States District Judge

Date: November 1, 2023